Testimony of Carol A. Heppe, District Director
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Mr. Chairman,

I want to thank you for inviting me to testify at this hearing on the reorganization of the Food and Drug Administration's (FDA) field offices.

I am Carol A. Heppe, District Director of FDA's Cincinnati District Office (CIN-DO). I have almost 35 years of service in FDA. My first 12 years were as an investigator in four field offices—Minneapolis; Portland, Oregon; Boise, Idaho; and Los Angeles. The next 14 years were in headquarters—Center for Food Safety and Applied Nutrition, Office of Legislative Affairs, and Office of Executive Secretariat. In 1999, I went back to the field as CIN-DO Director of Investigations Branch and later went into my current position.

In the afternoon of February 2, 2007, I received a call telling me that my job as District Director in CIN-DO was being eliminated due to the field reorganization.

On February 6, 2007, some information about the Office of Regulatory Affairs (ORA) field reorganization was provided at an ORA Senior Staff meeting in Maryland. Along with the lab closures, it was announced that the number of district offices in the field would be reduced from 20 to 16. Also, some district boundaries would be realigned. The plan given us was this: Cincinnati District (CIN-DO) would merge with Detroit District (DET-DO) with Detroit being the district office. New Jersey District (NWJ-DO) would merge with Philadelphia District (PHI-DO) with Philadelphia being the district office. Denver District (DEN-DO) would merge with Kansas City District (KAN-DO) with Kansas City being the district office. San Juan, Puerto Rico (SJN-DO) would merge with

Florida District (FLA-DO) with Florida being the district office. The realignment of district boundaries was: the states of Missouri and Iowa would be moved from KAN-DO to Chicago District (CHI-DO). Although I don't remember this being announced at the Senior Staff meeting, I later learned that the state of New Mexico was being moved from DEN-DO to Dallas District (DAL-DO).

We were not given information on how they reached this new structure. The one criterion I saw in a draft document and heard mentioned by a couple of managers was a goal of no district under 50 investigators. I did not hear any reason why 50 or more is the correct number for a district. It should be noted that with the hiring of investigators we are being authorized to do now, few to no districts will be under 50 investigators in the next year.

At this meeting, we were asked to do evaluations at the end of each day. A common complaint reported from the evaluations was that the communication on the reorganization has not been done well in the past year.

It is true that we have received several emails from the Associate Commissioner for Regulatory Affairs (ACRA) and have a Transformation Leadership Team (TLT) web site that we can go to for information. These have provided the broad goals ORA intends to achieve with the reorganization. However, there is nothing to tie these broad goals and intentions with the planned reorganization. In other words, field employees have not been given a justification or criteria, which have been used by those developing this reorganization, to indicate that this reorganization will result in achieving those goals.

We were also told that the reorganization included reducing the number of compliance branches from 20 to ten. We were not told where these compliance branches (CBs) would reside but were told which ones were merging. PHI-DO CB (containing NWJ-DO CB) and Baltimore District's (BLT-DO) would merge. DET-DO CB (containing CIN-DO CB) and CHI-DO's would merge. KAN-DO CB (containing DEN-DO CB) and Minneapolis District's (MIN-DO) would merge. DAL-DO CB and SW Import District's (SWID) would merge. Seattle District (SEA-DO) CB and San Francisco's (SAN-DO) would merge. Atlanta District (ATL-DO) CB and New Orleans District's (NOL) would merge. FLA-DO CB having merged with SJN-DO would have the CB. New York District (NYK-DO), New England District (NWE-DO), and Los Angeles District (LOS-DO) CBs would remain the same. We were told it had not been decided where the CBs would reside when merged.

For a better understanding of CBs, the compliance branch is one of two branches that have (at least during my time in FDA) been in an FDA district office. The other is investigations branch (IB). IB develops evidence for the enforcement cases through inspections, investigations, and sample collections. IB then writes a report tying the evidence together. The report is given to CB along with any sample results from an FDA lab to decide whether there is a viable case for writing an enforcement recommendation. Sometimes IB and CB disagree on whether there is a viable case. The District Director (DD) is ultimately responsible for deciding whether the recommendation for submission to HQ should move forward. As you can see, this could be quite problematic under the CB merger when there is a disagreement about a case between a district office that no longer has a compliance branch and the CB within another district.

In April 2007, ORA TLT Inspection Compliance Directorate implementation three member team (ICD) asked, in writing and during a teleconference, the district directors of the merging districts to develop and write a report to identify issues to be addressed in the merger/realignment, propose strategies and time lines to address those issues to make implementation successful, and ensure uniformity and minimize negative impacts on meeting core mission objectives during planning and implementation.

This implementation group, in writing and during a teleconference, also asked all Directors of the Compliance Branches (DCBs) and DDs to discuss obstacles and opportunities that need to be addressed for the new CB structure, propose strategies and solutions and timelines for implementation, effect a uniform transformation with minimum disruption of core functions, and keep the ICD in the loop. We were told that this new organization would save 80 FTE although it was not clear whether this was just from the CB reorganization or the whole field reorganization. We were not given any charts to demonstrate how these FTE would be saved.

The ICD gave an approximate June 1, 2007 due date for a finished report from both projects.

I actively worked in both groups. I was specifically on the compliance merger committee personnel and resource management workgroup, which reviewed the impact of the merger on personnel and ways to operate the new structure. This was one of seven groups in the compliance merger committee. It was around that time that we learned where the ten CBs would be located: PHI-DO, DET-DO, SEA-DO, KAN-DO, DAL-DO, ATL-DO, FLA-DO, NYK-DO, NWE-DO, and LOS-DO. We were not told the reason for locating the CBs in these district offices.

Our work on the district merging document indicated problems with the proposed new structure. We understood we were to work with the structure proposed because it had already been agreed to by ACRA Glavin. However, in reviewing the plan, there were some glaring issues with the boundaries and locations of the main offices. For example, it was clear to our group of DDs that KAN-DO should not be the district office site because it was on the extreme eastern edge of the new merged over 1000 mile across district that stretched through Utah; with Missouri going to CHI-DO, the split of the Kansas City inventory left little to be covered in the new DEN/KAN merged district, and inventory and case work shifted west making Denver the logical site for a district office.

Other questions came to mind:

- How would CHI-DO cover western Missouri firms with the current major office located and staffed in Lenexa?
- Should CHI-DO and KAN-DO have a partnership for KAN-DO to do the work for CHI-DO because it would save resources?
- Should CHI-DO have a small group of employees housed in the same office with the KAN-DO employees to do the work?

The complications and loss of efficiency in trying to make a border between Missouri and Kansas begged the question, why was Missouri put in CHI-DO and not kept with KAN-DO?

This led to a concern that there may be other unknown efficiencies related to the reorganization because we had not had time to look at all the issues. The problem we

found may have been avoided and possibly a better reorganization proposed if the group devising this plan had consulted the people who have the most knowledge of their districts—the DDs who manage them and their staff—before proposing the reorganization.

In the compliance merger committee meeting, which consisted of DCBs and DDs, we found it was difficult to proceed because our project was related to the results of other groups' projects such as the import group project. Our concern was we could be making decisions in a vacuum that may not coincide with another groups' decisions. The leader of our committee mentioned this concern to the ICD team. He reported back to us that we were just to continue our work.

Because of these concerns, the compliance merger committee's personnel and resource management work group, of which I was a member, submitted a document recommending that the reorganization be implemented by sequencing. We recommended that HQ be reorganized first, the districts next, with the compliance branches last. We questioned whether this proposal was the best fit and suggested a CB in each district to avoid conflicts with duel district management structures. We were concerned that having a CB reporting to one DD but doing work for up to three districts could create conflicts in case management. Who ultimately decides which cases have priority and which cases will go forward? We noted that the reorganization did not resolve the issue of the disparity of district and CB size, which we had been told at the February Senior Staff meeting, was the driving factor. Districts and CBs still varied greatly in size. Under the reorganization plan, some DCBs have as many as 17-18 employees reporting to them while others have as few as ten. Currently, on an average,

eight employees report to a DCB. I am not aware that our document was addressed by the ICD team although I was told at least two of the three ICD members saw it.

Furthermore, geographic dispersion of such a large supervisory group would only complicate matters. Managing this many employees would be difficult because they would be located in up to three offices, separated by hundreds of miles with the increased geographical area resulting from the mergers. This was noted as a grave concern in compliance merger committee discussions. Their report noted that employee morale is already being affected by the proposed reorganization because employees do not know where or what their next job is or will be.

In addition, ORA headquarters has expressed concern about the decrease in ORA's enforcement actions. Most of the field managers believe the CB merger will result in a further decrease. The DCB will have more employees' work to review and they may be located in up to three offices separated by wide geographical distances. It will also make interacting with firms much more difficult because they will be located further from the DCB (and DD where the districts have merged).

My discussions with other DDs and DCBs confirm widespread belief that these are major concerns for the workability of the CB merger. Furthermore, the role of the DCB has not been defined relative to ORA headquarters Office of Enforcement.

Regarding the field reorganization plan as a whole, I have the following concerns:

- It appears to be threatening our relationships with the states with which we often leverage resources.

- I understand that one of the states moving into CHI-DO has threatened to discontinue their inspection contracts with FDA unless they can continue to work with the KAN-DO employee. Loss of these vital inspections from any state places even more pressure on our districts.
- After the Association of American Feed Control Officials Board of Directors was briefed on the reorganization in the spring, concern was expressed about the distance they would be from FDA employees they need to work with on a continuous basis.
- Both Kentucky and Ohio state officials have told me that they prefer to have the district office remain in the much closer Cincinnati, OH.
- This is resulting in a disruption of important cultural and long term working ties the states have with the district they have been in.

- There has been no clarification of duties for the managers of these structures, and given the restructure, it is likely that many of the positions are not supportable under Office of Personnel Management (OPM) rules.
- Headquarters staffs appear to be building at the expense of the field forces which do the core functions of inspections, investigations, sampling and analysis.
- Lines of authority will be muddled due to cross servicing of the compliance units and integration of directions from headquarters in the import programs. Daily activities at the field level cannot wait for decisions and directions out of distant units, be they a consolidated compliance function or an import entry review unit directed by HQ.
- There is speculation that the development of only ten CBs is a prelude to reducing district offices further to ten. However, like most of the decisions on this reorganization, there is no open discussion on their basis and ultimate direction.

We were told the plan would go until 2011 so other changes must be under consideration.

- The current proposal could reduce our effectiveness at regulating an ever expanding and growing industry. ORA needs solid and effective leadership at all levels in the organization. We need managers and leaders who are well informed and conversant on the issues and compliance profile of firms around the country. Each state has its way of doing business; each industry has its characteristics. It is not the number of 50 investigators that should dictate the size of a district. Factors to use are industry concentrations; number of states; population centers; border coverage and type; cultural similarities of the states within the district; size of the various industries; travel distances; industry start up plans; and states prone to natural emergencies such as hurricanes. I believe it would be impossible to understand the implications of these factors from headquarters. And, it is not just about making decisions for a one-time reorganization. It is about the daily decisions that need to be made to manage our regulatory operations.
- The proposed reorganization will create confusion of direction, delay in implementation of programs, and sever many of our current working relationships with critical state and local governments and industry groups. Oversight of daily work will be difficult if not unachievable due to the overly wide span of control of the remaining managers. Concerns for quality of work do not appear to be addressed with this reorganization. We should not be making district offices larger and then correcting any problems with quality of work by adding more FTE in headquarters to review and correct it. We should address work quality issues where they originate.

- There is nothing to indicate that this proposal will result in our better serving our constituencies--the states, the industry, the broker and importer community and, ultimately, the consumer.

Furthermore, I am concerned that there is no indication that this reorganization will strengthen the way we regulate industry. As our emergencies have shown, we need to do a better job of regulating industry. I have not seen that any revisions made in the plan to strengthen our regulation of industry to prevent emergencies. Instead the reorganization continues as told to us in February--several districts will be increased in size and the number of CBs will be reduced. Those, who will be managing the emergencies locally, will have more industry to cover and thus greater potential for multiple emergencies and recalls, more cases to review and more personnel issues and union issues to resolve. They will be spread very thin, resulting in their having less time to concentrate on the work of consumer protection.

I am also concerned that many employees (managers and non managers) will retire or leave ORA because they disagree with the reorganization This will result in a mass loss of institutional knowledge and expertise at a time when the agency is trying to be proactive in our operations to prevent more emergencies. Then, couple that with a current increase in hiring and not having these experts to mentor and train the new hires while we carry on the daily business of consumer health protection.

These issues must be considered if FDA's public health mission is to be sustained.

This concludes my formal statement.